K061008

510(k) SUMMARY

Submitted By:

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SEP - 8 2006

Submission Contact: John D. Tamerius, Ph.D.

Date Prepared: April 11, 2006

Device Trade Name: QuickVue® RSV test

Common Name: Respiratory syncytial Virus (RSV) Test

Predicate Device: Binax NOW® RSV Test (K032166)

Device Classification/Name: 21 CFR 866.3480 / Respiratory syncytial virus serological reagents.

The device, the QuickVue® RSV test, is similar to other FDA-cleared devices used for the qualitative detection of RSV directly from clinical specimens. These tests are used to aid in the diagnosis of disease caused by respiratory syncytial viruses and provides epidemiological information on these diseases (21CFR 866.3480). The Food and Drug Administration has classified serological test systems for the detection of respiratory syncytial virus as Class I.

Intended Use: The QuickVue® RSV test allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) directly from nasopharyngeal swab, nasopharyngeal aspirate and/or nasal wash specimens for symptomatic patients eighteen years of age and younger. The test is intended for use as an aid in the rapid diagnosis of acute respiratory syncytial viral infections. Negative test results should be confirmed by cell culture. The test is intended for professional and laboratory use.

Physiologic Basis of the Test: Respiratory syncytial virus (RSV) is a single stranded (negative strand) RNA virus of the Paramyxoviridae family. It is the causative agent of a highly contagious, acute, viral infection of the respiratory tract. RSV infection is recognized as the leading cause of hospitalization of children during the first year of life. It is also the major viral cause of nosocomial illness in children already hospitalized for other reasons. Half of all infants become infected during their first year of life. Virtually all have been infected by their second year. Infection involving the lower respiratory tract carries an associated mortality rate of 0.5%, especially in premature infants or infants and children with underlying lung disease. There is a need for rapid diagnosis of RSV. This can lead to more effective care and management of these patients.

RSV causes approximately 100,000 hospitalizations and as many as 4,500 deaths in the U.S. each year. Recently, it has become more apparent that RSV is an important pathogen for the elderly and in the immuno-compromised patient.

The QuickVue® RSV test is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for RSV antigens. The test is specific to RSV antigen with no known cross-reactivity to normal flora or other known respiratory pathogens.

Device Description: Nasopharyngeal swabs, nasopharyngeal aspirate and/or nasal washes serve as specimens for this test. The patient specimen is placed in a tube containing Extraction Reagent, during which time the virus particles in the specimen are disrupted, exposing internal viral antigens. After extraction, the Test Strip is placed in the Extraction Tube for 15 minutes. During this time, the extracted specimen will react with the reagents in the Test Strip.

If the extracted specimen contains RSV antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the Test Strip. If RSV viral antigens are not present,

Device Description (cont.)

or present at very low levels, only a blue procedural Control Line will appear. If no blue procedural Control Line develops, the result is considered invalid.

Device Comparison:

Features	QuickVue® RSV Test	Binax NOW® RSV Test
Intended Use	The QuickVue® RSV test allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) directly from nasopharyngeal swab, nasopharyngeal aspirate and/or nasal wash specimens. The test is intended for use as an aid in the rapid diagnosis of acute respiratory syncytial viral infections. Negative test results should be confirmed by cell culture. The test is intended for professional and laboratory use.	The Binax NOW® RSV Test is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (RSV) fusion protein antigen in nasal wash and nasopharyngeal swab specimens from symptomatic patients. This test is intended for *in vitro* diagnostic use to aide in the diagnosis of RSV infections in neonatal and pediatric patients under the age of five. It is recommended that negative test results be confirmed by culture.
Specimen Types	Nasopharyngeal Swab Nasopharyngeal Aspirate and/or Nasal Wash	Nasopharyngeal Swab Nasal Wash
Extract / Elute	Extraction reagent used for swab/aspirate/wash	Transport liquid used for swab Wash – no dilution required
Read Result Time	15 Minutes	15 Minutes
Format	Lateral-flow immunoassay Dipstick	Lateral-flow immunochromatographic membrane assay Cardboard with book shaped hinge
Control Features	Procedural Control Line Clearing of Background	Procedural Control Line Clearing of Background
External Controls	Positive RSV swab RSV Negative swab coated with Streptococcus C antigen	Positive RSV swab RSV Negative swab coated with Streptococcus A antigen

Summary of Performance Data:

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to the predicate device. These studies included the following:

1. A multi-center field clinical study was conducted. Sensitivity, specificity and overall accuracy were calculated using nasopharyngeal aspirates and nasopharyngeal swabs compared to viral culture.
2. A clinical performance study with frozen nasal washes demonstrated the QuickVue® RSV gave excellent agreement with a predicate device presently marketed legally in the United States.
3. Physician's Office studies were conducted to demonstrate that physician office personnel with diverse educational backgrounds and work experience could perform the test accurately and reproducibly.
4. Analytical studies demonstrated lot-to-lot consistency, inter- and intra-lot precision, that common drugs and biologicals did not interfere with the test's performance, and that variations in the test method did not impact the test's performance.
5. A transport media study to select suitable media for the transport of clinical samples identified several transport media that performed optimally.

Conclusion:

These studies demonstrated the substantial equivalence of the QuickVue® RSV test to existing products already marketed. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 8 2006

John D. Tamerius, Ph.D.
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Quidel Corporation
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San Diego, CA 92121

Re: k061008
Trade/Device Name: QuickVue® RSV Test
Regulation Number: 21 CFR § 866.3480
Regulation Name: Respiratory syncytial virus serological reagents
Regulatory Class: I
Product Code: MCE
Dated: August 17, 2006
Received: August 21, 2006

Dear Dr. Tamerius:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

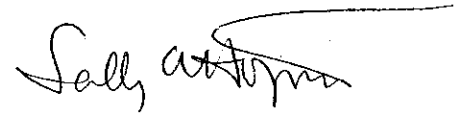
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061008

Device Name: **QuickVue® RSV test**

Indications for Use:

The QuickVue® RSV test allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) directly from nasopharyngeal swab, nasopharyngeal aspirate and/or nasal wash specimens for symptomatic patients eighteen years of age and younger. The test is intended for use as an aid in the rapid diagnosis of acute respiratory syncytial viral infections. Negative test results should be confirmed by cell culture. The test is intended for professional and laboratory use.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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